IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — **MDL No. 2327**

THIS DOCUMENT RELATES TO ALL WAVE ONE CASES INVOLVING THE PROLIFT LINE OF PRODUCTS

RULE 26 EXPERT REPORT OF DR. ABBAS SHOBEIRI

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

I. QUALIFICATIONS

Currently, I am a Professor of Obstetrics and Gynecology, Virginia Commonwealth University School of Medicine & George Washington University, Professor, Cell Biology & Anatomy, Graduate College, OUHSC, and Vice Chair, Gynecologic Subspecialties, Inova Fairfax Hospital Women's Center. Previously, I was Professor and Section Chief of Female Pelvic Medicine & Reconstructive Surgery at the University of Oklahoma Health Sciences Center. I am also a Professor of Cell Biology and Anatomy at the OUHSC.

I was recruited to the University of Oklahoma Health Sciences Center in 2002 as the first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery in Oklahoma. Prior to settling in Oklahoma, I obtained my Bachelor degree from the University of Washington in Seattle, Medical Degree from Tufts University in Boston,

and completed my residency and fellowship at Tulane and Louisiana State University in New Orleans. My CV is attached as Exhibit A.

I established the OU Pelvic and Bladder Health Center which now encompasses an ACGME accredited 3 year fellowship program, an International Continence Society and International Urogynecology Association host site for research scholar program, Pelvic Floor Investigation Group (PFIG), OU Basic Science Pelvic Floor Laboratory, and OU International Ultrasound workshop. I have been the recipient of research and educational awards. I have been a grant reviewer for the American College of Obstetrics and Gynecology, the American Urogynecologic Society, and American Federation for Aging Research. I am also a manuscript reviewer for Urology, Journal of Urogynecology & Pelvic Floor Dysfunction, American Journal of Obstetrics and Gynecology, Neurourology & Urodynamics, and Journal of Pelvic Medicine and Surgery. I have authored numerous articles in scientific journals as well as several chapters for textbooks standard to the field of Urogynecology. I am the editor of the textbook entitled: Practical Pelvic Floor Ultrasonography.

I have chaired ultrasound workshops at the International Continence Society, International Urogynecology Association, and multiple institutions around the world. Additionally, I have served on the Research and the Program committees at the American Urogynecologic Society.

My clinical interests include vaginal agenesis and structural abnormalities. My research interests include basic science neuroanatomy and the study of pelvic floor injury using 3D sonography. These include the evaluation and treatment of mesh-related complications.

II. BACKGROUND

The opinions expressed on this report are based on the peer-reviewed medical literature, as well as my experience as an academic urogynecologist with a busy clinical practice. As an academic urpogynecologist, I receive referrals from around the country for mesh-related complications. Patients with mesh-related complications are commonly referred to a tertiary care center for evaluation and treatment because the expertise for repair of these problems requires advanced training. In my current role as I am actively involved in patient care, teaching, and research.

In addition to my clinical practice treating pelvic organ prolapse and stress urinary incontinence and managing surgical complications, I have special expertise in the imaging of mesh with ultrasound technology. I am recognized as one of the world's experts in this area and have published widely in this area. This expertise provides me with a unique opportunity to visualize the behavior of mesh in vivo and correlate those findings with patient symptoms.

Numerous materials, biologic and synthetic, have been used to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Three-dimensional ultrasound has been shown to be the most effective technique to image these implantable materials. X-ray, CT scan, MRI are not capable of visualizing mesh, however 3D ultrasound rays bounce off the mesh material and make the mesh easily visible.

I popularized a technique for the optimal visualization of pelvic floor imaging of pelvic floor structures, including meshes and implants. The procedure used to obtain these images is similar to the traditional endovaginal sonogram, but the images are obtained using a side fire rather than an end fire transducer. The 3D volumes obtained by BK

transducer allows for optimal imaging of the vaginal wall, urethra, and anal canal. All images are obtained with a BK Medical 8838 high resolution, 6-12 MHz, 360° rotational transducer. The 8838 has a 65mm X 5.5mm acoustic footprint and penetration depth of up to 85mm. This transducer is similar in size and shape to the traditional end-fire transducer used in gynecological imaging. Pressing the 3D acquisition button moves the internal probe crystals to obtain images every 0.5 degrees for 360 degrees. The images are packaged into a 3D volume that can be manipulated in any plane. The 3D ultrasound imaging takes 30 seconds and minimizes patient discomfort. 2D Ultrasonography is typically operator dependent. 3D imaging allows for an automated acquisition. This reduces operator dependence; the data set is stored and can later be manipulated and analyzed. This methodology has been published and is now widely accepted by the medical community.

I am familiar with the Ethicon Prolift products, specifically, in addition to my knowledge relating to mesh products generally. I have personally managed patients with complications related to these devices and have removed Prolift mesh devices from patients referred to our center. Although approached by Ethicon as a "key opinion leader", I declined to continue using the Prolift devices because of the high rates and severity of complications seen in my practice, discussed at meetings with academic colleagues, and reported in the medical literature with prolapse mesh "kits". I have had my own patient who developed pudendal neuralgia after a posterior Prolift. Fortunately, I was proactive and after immediate removal of the Prolift, the pain resolved slowly.

IV. SUMMARY OF OPINIONS

1. Complications resulting from prolapse mesh "kits" like the Prolift products are unlike those seen with other pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment.
2. Three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications.
3. Mesh complications, including those resulting from the Prolift devices, are associated with distinct findings on EVUS.
4. Mesh findings on EVUS include deformation (bunching, folding, corrugation, curling, coiling, etc.), shrinkage and contraction, fragmentation, migration, and residual mesh.
5. Mesh contraction (defined by IUGA/ICS as shrinkage or reduction in size) is a well-known and well-accepted occurrence, can be detected by EVUS, and has clinical consequences.
6. The lateral arms of the Prolift devices are difficult, if not impossible to remove, even with the aid of advanced imaging and surgical skill, and result in significant morbidity for patients.
7. The Prolift devices are associated with an unacceptably high rate of complications, including erosion, chronic pain, vaginal scarring and distortion, and bladder, bowel, and sexual impairment.
8. EVUS evaluation combined with physical examination provides objective evidence of the mechanism and cause of mesh-related symptoms.

9. In a woman presenting with vaginal pain and sexual pain following a Prolift procedure, a mesh-related condition attributable to the mesh product is the most likely diagnosis on the list of differential diagnoses.
10. In a woman presenting with vaginal pain and sexual pain following a Prolift procedure, these symptoms are, more likely than not, associated with the properties of mesh described in this report.
11. The surgical management of mesh complications requires advanced training and specialized expertise.
12. Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients.
13. Most patients with mesh complications are referred for treatment by someone other than the implanting doctor. This indicates that complications are under-appreciated by community doctors and often results in a delay of appropriate treatment.
14. The Prolift devices are defectively designed as described in the body of this report.
15. Ethicon did not adequately warn physicians and patients about known complications and risks associated with its Prolift devices.
16. There are safer alternatives to the Prolift devics that have equivalent or superior efficacy.
17. Because of the rate and severity of complications and the lack of improved efficacy over other surgical procedures to treat pelvic organ prolapse, the risks of the Prolift devices outweigh their benefits and should not be used.

III. THE METHOD OF INSERTION FOR PROLIFT

My knowledge of the Prolift products as well as my review of Ethicon's Instructions for Use and insertion video provide the basis for this brief review of the method of insertion of the Prolift devices. These devices require transvaginal implantation of a pre-cut piece of polypropylene mesh using specially designed trocars. The Prolift anterior and posterior products are comprised of a central mesh portion and four flat mesh arms.

The images below from the original Prolift IFU depict the devices and the insertion methods. A document that I had in my possession describing the Surgical Technique involved in the Prolift procedures is also attached to this report. This is a complex operation even for experienced pelvic floor surgeons and should not be considered "minimally invasive." This is also borne out in the peer-reviewed medical literature.[1]

[1] D. Altman and C. Falconer, "Intra and Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair," *Obstet Gynecol* 109, no. 2 Pt 1 (2007).

ENGLISH

Gynecare

PROLIFT*

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT* Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training.

Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair Systems for further information on the GYNECARE PROLIFT procedures.

INDICATIONS

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

DESCRIPTION

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT Pelvic Floor Repair System Components

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1)*.

Anterior Mesh Implant

The Anterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1)*.

Posterior Mesh Implant

The Posterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1)*.

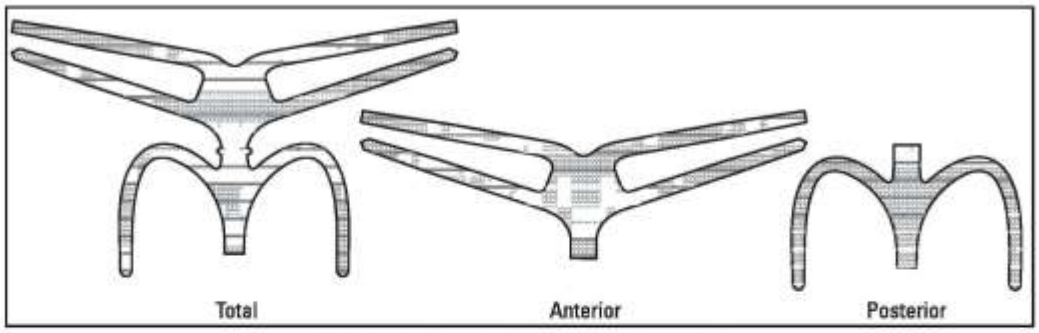


Figure 1 – Mesh Implants (Total, Anterior, and Posterior)

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient *(see Figure 2)*.

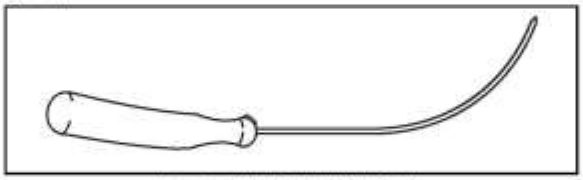


Figure 2 – GYNECARE PROLIFT Guide

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn *(see Figure 3)*.

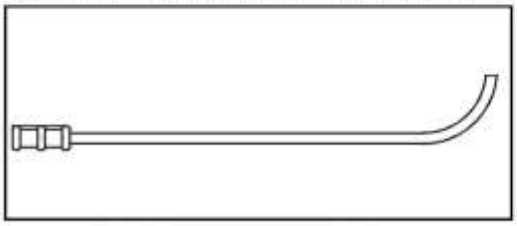


Figure 3 – GYNECARE PROLIFT Cannula

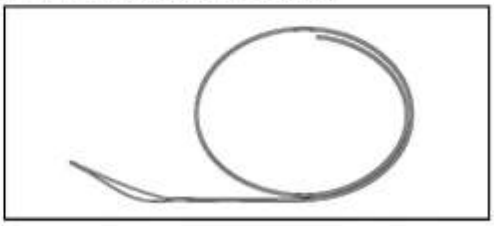


Figure 4 – GYNECARE PROLIFT Retrieval Device

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula *(see Figure 4)*.

INSTRUCTIONS FOR USE

NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the the GYNECARE PROLIFT Cannula onto the GYNECARE PROLIFT Guide *(See Figures 5A and 5B)*

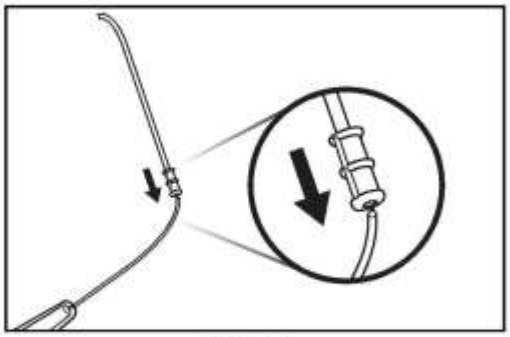


Figure 5A

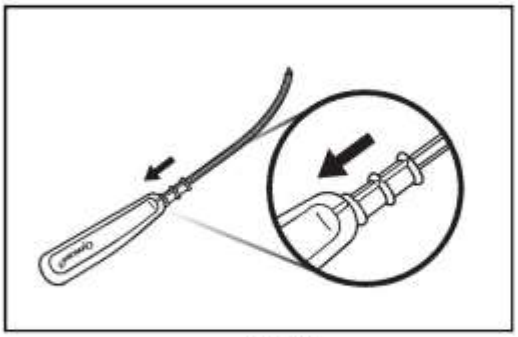


Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT Cannula and GYNECARE PROLIFT Guide upon assembly as demonstrated in *Figure 5B*.

Placement of the GYNECARE PROLIFT Cannula into the Patient *(See Figures 6A , 6B and 6C)*

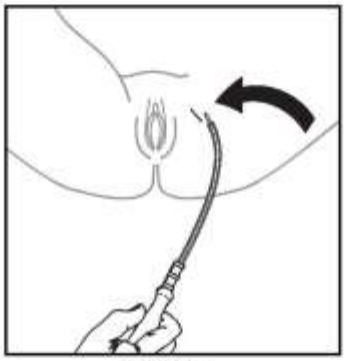


Figure 6A

Figure 6B

Figure 6C

Insertion and Passage of the GYNECARE PROLIFT Retrieval Device into the GYNECARE PROLIFT Cannula *(See Figures 7A and 7B)*

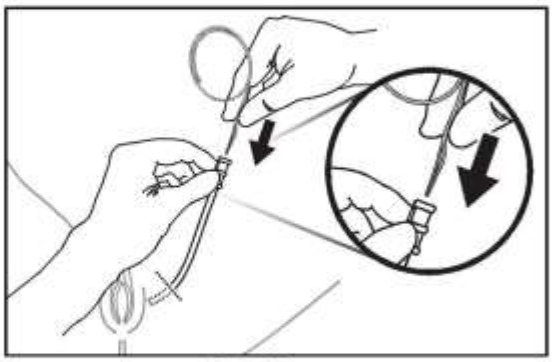


Figure 7A

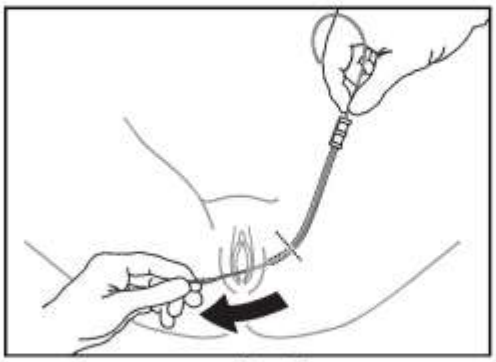


Figure 7B

IMPORTANT: All provided GYNECARE PROLIFT Cannulas and GYNECARE PROLIFT Retrieval Devices should be placed prior to mesh implant installation.

4

Capture of a Mesh Implant Strap with GYNECARE PROLIFT Retrieval Device ***(See Figures 8A , 8B and 8C)***

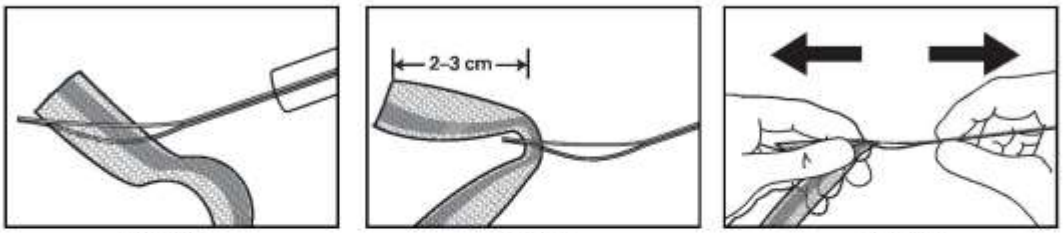


Figure 8A *Figure 8B* *Figure 8C*

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT Cannula ***(See Figures 9A , 9B and 9C)***

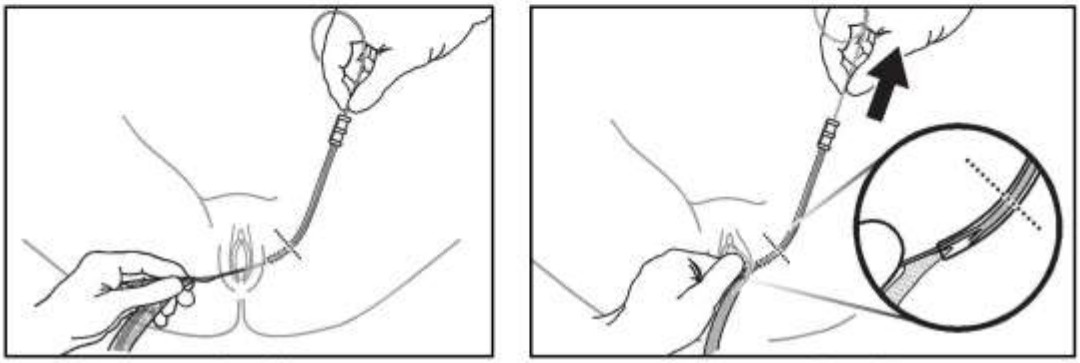


Figure 9A *Figure 9B*

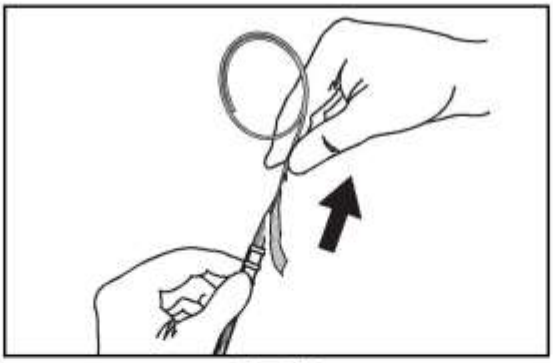


Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT Cannulas from the patient until the mesh implant has been properly positioned.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

PERFORMANCE

Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

CONTRAINDICATIONS

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.
- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

STERILITY

The GYNECARE PROLIFT Pelvic Floor Repair Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

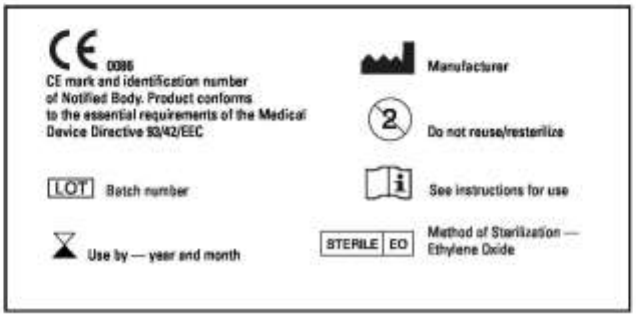
DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

Symbols Used on Labeling



6

The anterior prolift is implanted by blindly passing trocars inward through the perineal skin incisions, adductor muscles, obturator foramen, obturator internus, and/or levator ani, out through a mid-vaginal incision, then by attaching the mesh arms to a snare device in the trocar, and pulling the trocar with each arm of the mesh outward into place, thereby placing the central portion of the mesh either between the bladder and anterior vaginal wall (anterior Prolift) or between the rectum and the posterior vaginal wall (posterior Prolift). The anterior Prolift products require four trocar passages through the transobturator space and separate incisions. The posterior Prolift products requires two trocar passages via the transgluteal space through the sacrospinous ligament and the pudendal nerve territory.

As the Prolift mesh arms are being pulled into place, the tension may cause deformation and curling of the arms, altering the shape of the arms and the size and shape of the pores of the arms. There is no way to place these devices in a "tension-free" manner. The polypropylene mesh arms pass through muscle and densely innervated tissue and are intended to scar into place. The edges of the Prolift devices are sharp and are known to exhibit a "sawing effect" as the sheath is removed and the arms pass through delicate tissue, resulting in tissue damage.

V. DISCUSSION

When one looks at the older urogynecology textbooks, the complications of surgical procedures were mostly limited to postoperative medical complications such as postoperative bleeding, pulmonary embolus, myocardial infarctions, and deep venous thrombosis. With the introduction of synthetic materials and mesh kits into vaginal reconstructive surgery over the past decade, unprecedented complications have occurred.

Although the frequency and severity of these complications were unexpected, they were foreseeable based on the hernia literature and known properties of polypropylene including chronic inflammation, foreign body reaction, shrinkage/contraction, hardening, nerve entrapment, deformation, and degradation. These are often difficult to manage and require innovative solutions.[2]

The placement of mesh increased rapidly in POP and stress incontinence surgery; however, many complications occurred due to inappropriate techniques dictated by the devices, and many complications were recognized too late and were poorly managed. Many of these techniques, including the Prolift devices, placed mesh through muscles and densely innervated areas where gynecologic surgeons were not accustomed to operating. Complications unique to mesh (vaginal mesh extrusion, urinary tract erosion, and mesh contraction) are being reported with increasing frequency.[3] Some of these complications are new and unique and require innovative surgeries that may or may not correct the problem. Symptoms of suspected vaginal mesh complications include vaginal discharge and/or bleeding, dyspareunia, pelvic pain, and recurrent urinary tract infections.

The most common complications associated with mesh procedures, in our experience and as reported in the medical literature, are pain, dyspareunia, erosion, and de novo urinary tract symptoms.[4] These complications are very different from those seen in

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[2] Giulio Santoro, MD, Pawel Wieczorek, MD, and S. A. Shobeiri, MD. *Endovaginal Three Dimensional Sonography*. Pelvic Floor Disorders 2010.

[3] Abed, H., et al. (2011). "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review." Int Urogynecol J 22(7): 789-798; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[4] Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol **210**(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from

native tissue pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment. Vaginal mesh exposure, contraction and other complications can be serious and are associated with substantial morbidity. They may result in pelvic/vaginal pain on movement and dyspareunia. In addition, delay in diagnosis can cause chronic problems, which are difficult to treat even after the removal of the mesh.[5] Ultrasound has shown exceptional sensitivity and specificity over physical examination for detection of vaginal mesh (Manonai). Persistent pain after mesh implantation is a serious matter. It is, most commonly, the consequence of nerve entrapment or damage, mesh contraction, and scarring. Surgical intervention is often required to alleviate symptoms. It basically involves mobilization of the mesh, division of the fixation arms, and excision of contracted mesh. Apart from possible irreversible damage to the nerve in the case of nerve injury, secondary vaginismus and pelvic floor muscle spasm may occur. Secondary vaginismus is caused by the woman's fear of the pain and is quite difficult to treat.[6]

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pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J **25**(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.; FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm; Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." Neurourol Urodyn 30(1): 2-12; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman**:** 87-105; Brubaker, L. and B. Shull (2012). "A perfect storm." Int Urogynecol J **23**(1): 3-4.

[5] J. Manonai et al., "Clinical and Ultrasonographic Study of Patients Presenting with Transvaginal Mesh Complications," *Neurourol Urodyn* (2015).

[6] Marcus-Braun, N. and P. von Theobald (2010). "Mesh removal following transvaginal mesh placement: a case series of 104 operations." Int Urogynecol J 21(4): 423-430; von Theobald P. Place of mesh in vaginal surgery, including its removal and revision. Best Pract Res Clin Obstet Gynaecol 2011; 25:197–203; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

Several groups have published widely on the evaluation and management of mesh complications. In 2012, our group reported on 133 patients who presented to our clinic for complications of vaginal mesh. The median number of complications per patient was three. The most commonly reported complication was exposure of mesh into the vagina (63.1%). Other complications included: pain (42.8%), infected mesh (6%), dyspareunia (38.3%), vaginal bleeding (24.8%), vaginal discharge (27%), stress urinary incontinence recurrence (29.3%), and pelvic organ prolapse recurrence (25.5%). Some patients had multiple complications. From this study, we determined that the majority (79%) of the patients presenting to our facility were referred by a physician other than the original vaginal mesh surgeon. In our study, the majority of patients with complications secondary to implantation of vaginal mesh who underwent reoperation at tertiary care centers were referrals and had the original implantation performed elsewhere.[7]

We recently reported a clinical and ultrasonographic study of patients presenting with transvaginal mesh complications which included 79 patients. Of these, 51.9% had vaginal/pelvic pain and 82.2% of sexually active patients had dyspareunia. In this study, we determined that endovaginal ultrasound (EVUS) was helpful in the diagnosis and management of mesh complications.[8]

Multiple publications have determined that three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications. Mesh complications are associated

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[7] Rostaminia, G., et al. (2012). "Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic." J Okla State Med Assoc 105(9): 356-358.

[8] Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

with distinct findings on EVUS.[9] MRI and X-ray imaging have been found to be inferior in their ability to visualize graft materials when compared with ultrasound.[10] They may visualize the swelling and edema around the mesh but not the mesh itself. Three-dimensional endovaginal ultrasound is a useful tool to evaluate outcomes of surgery with implants, delineate the reason for complications or failure, and plan treatment, especially in patients with a complicated treatment history.[11]

EVUS can be used to determine the location of a mesh device, as well as its deformability and movement with Valsalva. These findings correlate with surgical outcomes. [12] In another abstract submitted for publication at 2016 American Urogynecologic Society meeting, we describe various mesh patterns associated with pain and extrusion. Multicompartment imaging is useful in determining the location and

[9] e.g. Shobeiri A Practical Floor Ultrasonography Springer 2014; Santoro G, Wieczorek A, Shobeiri S, Mueller E, Pilat J, Stankiewicz A, et al. Interobserver and interdisciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. Int Urogynecol J. 2010;22:53–9; Santoro GA, Wieczorek AP, Dietz HP, Mellgren A, Sultan AH, Shobeiri SA, et al. State of the art: an integrated approach to pelvic floor ultrasonography. Ultrasound Obstet Gynecol. 2011;37:381–96; Santoro GA, Wieczorek AP, Stankiewicz A, Wozniak MM, Bogusiewicz M, Rechberger T. High-resolution three-dimensional endovaginal ultrasonography in the assessment of pelvic floor anatomy: a preliminary study. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20(10):1213–22. PubMed PMID: 19533007. [English]; Chantarasorn V, Shek KL, Dietz HP. Sonographic appearance of transobturator slings: implications for function and dysfunction. Int Urogynecol J. 2011; 22:493–8; Santoro GA, Wieczorek AP, Shobeiri SA, Mueller ER, Pilat J, Stankiewicz A, et al. Interobserver and interdis- ciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. Int Urogynecol J Pelvic Floor Dysfunct. 2011;22:53–9; Santoro GA, Wieczorek AP, Shobeiri SA, Stankiewicz A. Endovaginal ultrasonography: methodology and normal pelvic floor anatomy. In: Santoro GA, Wieczorek AP, Bartram CI, editors. Pelvic floor disorders: imaging and multidisciplinary approach to management. Dordrecht: Springer; 2010. p. 61–78; Santoro GA, Wieczorek AP, Bartram C. Pelvic floor disorders: imaging and multidisciplinary approach to management. 1st ed. Italia: Springer; 2010. p. 729; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[10] Hegde, A. and Davila, G. W.. Endovaginal Imaging of Vaginal Implants. S. A. Shobeiri: 133-152.

[11] *Id.* at 134.

[12] *Id.* at 139.

function of synthetic implants.[13] It can help clarify the symptoms of pain and erosion associated with mesh implants. It is also useful in patients with a history of mesh surgery in whom the exact nature of the surgery or the site of mesh placement is unknown. Imaging can be performed preoperatively to understand the intrapelvic course of the mesh implant in order to plan mesh revision surgery better. It can also be performed following mesh removal surgery to determine if there is any mesh left behind.[14] Common mesh findings on EVUS include deformation (flatness, folding, coiling, prominence, and etc.), shrinkage and contraction, fragmentation, migration, and residual mesh.

The mechanisms leading to pain after mesh placement for prolapse is multifactorial. A combination of nerve or muscle damage/entrapment and/or tension on vaginal or perivaginal structures as a result of retraction and scarring are probable explanations. These are findings regularly confirmed on ultrasound and histological examination. For example, Feiner and Maher defined a series of 'mesh contraction' in 17 women surgically managed with mesh excision. All subjects presented with intractable pelvic pain, dyspareunia and tenderness on pelvic examination associated with vaginal scarring.[15] Velemir reported a series of Prolift implants, correlating severe mesh retraction seen ultrasonographically with anterior wall prolapse recurrence.[16]

[13] *Id.* at 144.
[14] *Id.*
[15] Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330.
[16] Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006.

Mesh contraction is reported extensively in the medical literature.[17] The FDA, in its 2011 PHN states "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*.[18] Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." The ICS/IUGA Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prostheses (Meshes,

[17] Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174; Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. (1998). "Shrinking of polypropylene mesh in vivo: an experimental study in dogs." The European Journal of Surgery 164(12): 965-969; Deffieux, X., et al. (2007). "Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study." Int Urogynecol J Pelvic Floor Dysfunct 18(1): 73-79; Klosterhalfen, B., et al. (2005). "The lightweight and large porous mesh concept for hernia repair." Expert Rev Med Devices 2(1): 103-117; Gonzalez R., F. K., McClusky D 3rd, Ritter E.M., Lederman, A., Dillehay D. (2005). "Relationship between tissue ingrowth and mesh contraction." World J Surg 29: 1038-1043; Garcia-Urena, M. A., et al. (2007). "Differences in polypropylene shrinkage depending on mesh position in an experimental study." Am J Surg 193(4): 538-542; Gauruder-Burmester, A., et al. (2007). "Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse." Int Urogynecol J Pelvic Floor Dysfunct 18(9): 1059-1064; Tunn, R., et al. (2007). "Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele." Ultrasound Obstet Gynecol 29(4): 449-452; Margulies, R. U., et al. (2008). "Complications requiring reoperation following vaginal mesh kit procedures for prolapse." Am J Obstet Gynecol 199(6): 678 e671-674; Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330; Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006; Mamy, L., et al. (2011). "Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection." Int Urogynecol J 22(1): 47-52; Letouzey, V., Mousty, E., Huberlant, S., Pouget, O., Mares, P., de Tayrac, R. "Utrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Anterior Bilateral Sacro Spinous Ligament and Arcus Tendinous Suspension." J Minim Invasive Gynecol 17(6): S7–S8; Lefranc, O., Bayon, Y., Montanari, S., *et al.* (2011) Reinforcement Materials in Soft Tissue Repair: Key Parameters Controlling Tolerance and Performance-Current and Future Trends in Mesh Development. In: Von Theobald, P., *et al.*, Eds., *New Techniques in Genital Prolapse Surgery*, Springer Verlag London Ltd., London.

[18] FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

Implants) and Grafts in Female Pelvic Floor Surgery lists mesh contraction and defines it as "shrinkage or reduction in size."[19] "Prominence" is defined as "parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial separation).[20] Although there is one article in the medical literature by Dietz that questions the evidence for mesh contraction, the methodology in this publication is seriously flawed and does not represent generally held opinions.[21]

There are symptoms and conditions that are unique to mesh. For example, exposure and erosion are only seen with synthetic mesh devices. There are also pain syndromes that are unique to mesh. These are often associated with characteristic findings on ultrasound and pelvic examination. When a patient presents with vaginal pain and sexual pain following a mesh procedure, this condition, more likely than not, is caused by mesh and, more likely than not, is mediated by one or more of the mechanisms discussed in this report. The reason is that mesh produces a unique constellation of symptoms that are characteristic of the presence of mesh and virtually not seen in any other setting. Although a differential diagnosis requires looking at all possible explanations for a given constellation of symptoms, there are very few, if any, other medical conditions that produce the same symptoms as mesh – especially when considered in aggregate.[22]

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[19] Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." Neurourol Urodyn 30(1): 2-12.

[20] *Id.*

[21] Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174.

[22] FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman**:** 87-105; Lee, D., et al. (2014). "Meshology: a

Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients. Unfortunately, doctors in the community are often not aware of the risks of mesh. Complications are underreported. Although mesh insertion seems like an easy procedure, the treatment of complications is challenging and surgical management may require specialized expertise. Even in the best of hands, many patients will continue to have symptoms after removal of mesh. Pain is the most difficult condition to treat effectively. The arms of prolapse mesh kits (like the Prolift devices) are particularly problematic and difficult, if not impossible, to remove in their entirety.[23]

From a clinical perspective, the Prolift products are defectively designed. Features of these products rendering the products defective include the following:

1. The blind passage of synthetic mesh arms through muscle and densely-innervated tissue, resulting in tissue damage and trauma.

2. The high, asymmetrical, and unpredictable degree of shrinkage/contraction of the device including the arms.

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fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Novara, G., et al. (2010). "Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence." Eur Urol 58(2): 218-238; Bako, A. and R. Dhar (2009). "Review of synthetic mesh-related complications in pelvic floor reconstructive surgery." Int Urogynecol J Pelvic Floor Dysfunct 20(1): 103-111; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Dunn, G. E., et al. (2014). "Changed women: the long-term impact of vaginal mesh complications." Female Pelvic Med Reconstr Surg 20(3): 131-136; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[23] Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Danford, J. M., et al. (2015). "Postoperative pain outcomes after transvaginal mesh revision." Int Urogynecol J 26(1): 65-69; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130. Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470.

3. The failure of the central portion of the mesh device to lie flat when there is tension from the arms.

4. The difficulty or impossibility of removing the entire device when complications warrant.

5. The need for multiple surgeries to remove the mesh.

6. The chance of persistent symptoms, especially pain, even after the device has been removed.

7. The late onset of complications that may occur indefinitely into the future.

8. The products cause chronic pain syndromes (resulting from nerve entrapment, scarring, mesh deformation and contraction and inflammation), that are often extremely difficult to treat

I have reviewed and am familiar with the Instructions for Use for the Prolift products.[24] I have also reviewed the IFUs for many other medical products throughout my career. To make an informed decision of whether or not to use a particular product, the physician must be warned not only of the potential adverse events that may be associated with the product, but also the frequency, severity, duration and potential permanence of those adverse events. In addition, doctors need this information to adequately inform their patients of the risks and benefits of a given treatment option.

Ethicon's Prolift IFUs are inaccurate, misleading, and incomplete. As such, they do not inform doctors and patients of the true risks associated with the Prolift devices. The IFU states that the "bi-directional elastic property allows adaptation to various stresses encountered in the body". I found no evidence supporting this claim, nor is it consistent with the medical literature or my experience. The IFU states that "animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight

[24] ETH.MESH.02341658; ETH.MESH.02341522; ETH.MESH.02341454; ETH.MESH.02001398.

inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." I did not see animal studies that were long-term or with mesh implanted in the vagina of an appropriate model. Nor did I see human studies supporting this claim. This statement contradicts the medical literature and my experience.

Nowhere do the IFUs address the severity, frequency, unresponsiveness to treatment, or the permanence of complications. The IFUs minimize the risks by stating that "potential adverse reactions are those typically associated with surgically implantable materials". This is simply not the case. In a 2009 update, the IFU also trivialized the severe complications seen with the Prolift devices by stating that "potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve in time."[25]

I have personally observed and treated patients who have been implanted with Prolift products. Sadly, my own patients have had Prolift related complications. I have seen patients who have experienced the following device-related complications, often severe and life-altering:

- Chronic pain syndromes;
- Chronic inflammation of tissue surrounding mesh;
- Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;

[25] ETH.MESH.02001398.

- Erosion of mesh into the bladder and rectum and recurrent exposure of mesh in the vagina;
- Pudendal neuralgia;
- Pelvic floor muscle spasm;
- Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging;
- Dyspareunia and sexual impairment, sometimes permanent;
- Constipation or fecal incontinence;
- Deformed, wrinkled, folded, curled, roped, degraded and fragmented mesh upon removal and visualized with ultrasound;
- Encapsulation of mesh (mesh covered in thick scar);
- Vaginal shortening, tightening, stenosis and/or other deformation;
- Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;
- Vaginal erosion and extrusion and visceral erosion;
- De novo urinary symptoms;
- "Hispareunia".

The published medical literature also reports these same types of complications with transvaginal pelvic organ prolapse repair implants.[26] Clinical trials would have shown

[26] Hansen, B., et al., *Long-Term Follow-up of Treatment for Synthetic Mesh Complications*, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair.* Surg Technol Int. 2014, 24:217-24.; Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., *The use of mesh in vaginal prolapse repair: do the benefits justify the risks?* Current Opinion in Urology 2010, 20:275-279; Blandon, et al., *Complications from vaginally placed mesh in pelvic reconstructive surgery*, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Int Urogyn J, 2009, 20:893-6; Margulies et al, *Complications*

that functional outcomes are inferior with transvaginally placed armed mesh when compared with non-mesh procedures.

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, it is my professional opinion to a reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed and treated associated with the Prolift products are directly attributable to the defective design of these products as described previously.

The IFU should have warned about the potential for the mesh to cord, buckle, wrinkle, deform, and degrade, the potential for permanent pain as a result of the mesh, and the potential of multiple tedious, difficult, and risky surgeries in the event the mesh needed to be removed. Having read and relied upon IFUs for medical devices during my career**,** it is my opinion that the type of information detailed above should be communicated to surgeons so that they can make safe treatment choices for their patients. If physicians are not fully and timely informed of all of the information known to the manufacturer concerning the safety of the product, they cannot be expected to perform an adequate risk-benefit analysis or obtain informed consent from their patients.

The design of the Prolift products is defective. As the mesh arms scar into tissue and deform, they can pull asymmetrically on the central portion of the mesh. This can result in the bunching, folding or wrinkling of the center mesh portion, which is intended to stay flat. This often causes pain and can lead to erosion or extrusion of the mesh through the vaginal mucosa. The arms of the mesh pull on their anchoring points in the pelvic sidewall muscles (obturator, sacrospinous ligament and levator ani) and tend to pull these

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requiring reoperation following vaginal mesh kit procedures for prolapse, Am J Obstet Gynecol December 2008.

anchoring points and the attached muscles or underlying nerves toward the midline. This pulling can be asymmetrical, non-uniform and pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing and straining. Attempts at defecation or sexual penetration push on the mesh, aggravating the pulling on the arms, which in turn causes new or worsening pain. During many normal activities, pressure is placed on the mesh, which is transmitted to the attachments in the pelvic sidewall and entrapped scarred nerves, also deforming and pulling on the muscle and nerves at the attachment points. This is something I frequently observe in my practice and is reported in the medical literature.

As the central portion and arms of the Prolift devices scar in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves and nerve branches and result in severe, permanent and difficult-to-treat or untreatable pain as a result of the chronic inflammatory response and fibrosis.[27]

It is extremely difficult and traumatic to attempt to remove all of the Prolift mesh once it has been implanted. It is virtually impossible to remove all of an armed transvaginal mesh implant. There is no evidence that Ethicon ever considered what should be done if the mesh caused complications and all or part of the mesh needed to be removed. The inability to remove all of the mesh can cause long-lasting complications, including chronic pain. Surgeries to attempt to remove pieces of the mesh increase the presence of

[27] Smith T, et al., Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center. Female Pelvic Med Reconstr Surg 2013; 19:238-41; Klosterhalfen, et al., The Lightweight and Large Porous Mesh Concept for Hernia Repair. Expert Rev. Med. Devices 2(1) 2005; Castellanas ME et al., Pudendal Neuralgia After Posterior Vaginal Wall Repair with Mesh Kits: An Anatomical Study and Case Series. Journ Minimally Invasive Gynecol 19 (2012) S72.

scar tissue, which can create or contribute to the patient's pelvic pain, dyspareunia and normal function of the pelvic area.

In designing a pelvic repair mesh product intended to be sold and implanted by physicians like myself, a reasonable device manufacturer must consider and weigh all of the known risks versus the benefits of a particular design, as well as all information known to the manufacturer that may bear on the safety and efficacy of the design, including the gravity, severity, likelihood, and ability to avoid of the dangers associated with the design.

The armed, blind trocar-based implantation methodology is an inherently flawed part of the design of the Prolift products. If mesh is used, there are safer implantation designs available, including abdominal / laparoscopic sacrocolpopexy. I perform abdominal or laparoscopic sacrocolpopexy (SC) procedures using mesh. The SC procedure is designed to address prolapse in the apical, anterior, and posterior pelvic floor. The SC uses a "Y" shaped implant to lift the vaginal apex, anterior, and posterior walls to a position inside the pelvic cavity, by attaching the mesh to the apex of the vagina, and attaching the other end of the mesh to a ligament overlying the sacral promontory. Implants used in sacrocolpopexy are passed into position via an abdominal incision, and are not exposed to the bacteria and other organisms in the vagina. Thus, the potential for microbial contamination of the SC mesh is greatly decreased.

Implants used as reinforcement in SC are anchored in a vertical direction, and are not attached to the muscles in the pelvis. When abdominally placed mesh contracts during normal healing, this tends to result in a pulling up, or lengthening of the vagina, without the pain associated with pulling on muscle with the Prolift devices. Also, by placing the mesh abdominally instead of transvaginally, the risk for infection, excessive inflammatory

response, delayed healing and erosion is reduced. The mesh placed for SC behaves differently is safer than transvaginally implanted Prolift products. Products designed for SC implantation are safer, feasible alternatives to transvaginal mesh kits like the Prolift mesh products.

The fact that polypropylene mesh has been used for hernia repair in the abdomen does not establish or support its safety or efficacy for use in the female vagina. Unlike the abdomen, the vagina is multi-planar and subject to multidirectional forces. The vagina is composed of delicate, sensitive tissue. It is a functional organ and its function relies on its movement. Placing a large piece of mesh under the bladder or over the rectum attached to fixed points in the pelvis eliminates the vagina's capacity for movement and functionality.

In my interactions with Ethicon representatives, I expressed my concerns regarding the lack of clinical data. Patients are not more satisfied with armed mesh as compared to traditional repairs. And, in studies comparing the anatomical success of TVM with traditional repairs, the notion of what is a successful repair depends upon the different definitions of "success" given by different authors.

When the definition of successful prolapse repair surgery includes both anatomic and functional outcomes, it is now clear that the risk of TVM surgery is greater than the benefit. In my experience with vaginal mesh kits, I had more blood loss, more adverse events such as pudendal neuralgia and unpredictable anatomic results. This is reported in the medical literature as well. Transvaginal mesh has a higher re-operation rate than native tissue repair due to the rate of surgeries for attempted repair of complications.[28]

[28] de Tayrac R et al., Complications of POP Surgery and Methods of Prevention, Int. Urogynecol. J. 2013; 24:1859-1872.

It is also now clear that there is no functional or anatomic benefit for TVM in the posterior compartment [29] TVM may offer improved anatomical outcomes for polypropylene mesh compared with anterior native tissue repair. However, these outcomes do not translate into improved functional outcomes or a lower reoperation rate for prolapse. The mesh group is associated with increased morbidity, mesh extrusion, and higher reoperation rates.[30]

In a double-blind randomized trial comparing vaginal prolapse repair with and without mesh, there was no difference in anatomic benefit at three years; and there was a 15% mesh exposure rate after three months.[31]

To summarize, there is no good evidence supporting benefit in quality of life or relief of symptoms in any compartment with the use of TVM to treat pelvic organ prolapse, and many of the complications of TVM surgery are likely to be more frequent and more severe, unlike those seen with traditional prolapse repairs.

It is also my opinion that the information available to Ethicon in the scientific literature (and Ethicon's internal documents) concerning the potential for polypropylene degradation should have prompted Ethicon to conduct clinical studies to determine whether naturally occurring conditions in the pelvis and vagina could cause the polypropylene mesh to degrade and, if so, to establish what the clinical implications for patients would be.

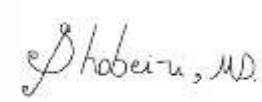
[29] Karram M, Maher C, Surgery for Posterior Wall Prolapse. Int. Urogynecol. J. 2013; 24(11): 1835-41.
[30] Maher C, Anterior Vaginal Compartment Surgery. Int. Urogynocol. J. 2013; 24:1291-1802; Ostergard D, Evidence-based Medicine for Polypropylene Mesh Use Compared with Native Tissue Repair. Urology 79: 12-15, 2012.
[31] Gutman et al., Three-Year Outcomes of Vaginal Mesh for Prolapse. Obstet Gynecol 2013; 122:770-7.

Ethicon's physician training program for the Prolift products was inadequate, and resulted in Ethicon's "certification" of numerous physicians who were undertrained and who lacked the experience, skills and expertise necessary to properly perform the implantation of these products.[32] Ethicon's documents reflect that Ethicon did not consider physician training to be a priority, or even a necessity.[33]

My personal experience with Ethicon was that I was approached as a "thought leader" to perform the Ethicon procedures. Identifying the "thought leaders" in the community was a popular industry strategy in convincing the community physicians to use their products which in part lacked credible efficacy and safety evidence. I did perform a few Prolifts all of which were associated with complications. I approached these complications quickly and resolved them by removing the mesh, but I have seen community physicians not properly informed of the complications, let the complications linger.

Particularly in light of Ethicon's knowledge about the risks inherent in the design of its products which Ethicon's internal documents specifically recognize, Ethicon's design of the Prolift products was unreasonably dangerous and defective. The Prolift devices failed to perform as safely as a patient or physician would expect when implanted in the intended manner, and the probability of a serious complication developing was so high that the risk of using the product outweighed any potential benefit.

Dated: January 29, 2016



S. Abbas Shobeiri, M.D.

[32] ETH.MESH.00005098; ETH.MESH.00847816; ETH.MESH.0409664; ETH.MESH.01184119.
[33] ETH.MESH.00031538-00031560 ("Professional Education Events . . . Indicated by market analysis . . . Must have strong case for "Return on Investment"); ETH.MESH.00005098.

Additional Reliance Materials

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Altman, D., and C. Falconer. "Intra and Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair." *Obstet Gynecol* 109, no. 2 Pt 1 (Feb 2007): 303-8.

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Exhibit A

S. Abbas Shobeiri, M.D., FACOG, FACS, CMPE

Vice Chair, Gynecologic subspecialties
Inova Fairfax Hospital
Professor of Obstetrics & Gynecology^*
Adjunct Professor of Cell Biology*
The University of Oklahoma Health Sciences Center*
George Washington University^
Virginia Commonwealth University^

www.linkedin.com/pub/s-abbas-shobeiri/3/274/99a/en

Contents

EDUCATION AND TRAINING:

Board Certification	Female Pelvic Medicine and Reconstructive Surgery, FACOG	2013-
	Obstetrics and Gynecology	2003
Professional Certification: Certified Medical Practice Executive		2014
	CUCOG (The Council of University Chairs of Obstetrics and Gynecology) leadership development program	2015-17
Fellowship	Female Pelvic Medicine and Reconstructive Surgery Fellowship Louisiana State University Health Sciences Center New Orleans, LA	1999-2002
Residency	Obstetrics and Gynecology Louisiana State University Health Sciences Center New Orleans, Louisiana	1995-1999
Internship	Internal Medicine Tulane University New Orleans, Louisiana	1994-1995
Graduate School	Executive Healthcare Master of Business Administration Brandeis University Boston, Massachusetts	2016-2017
Medical School	Doctor of Medicine Tufts University School of Medicine Boston, Massachusetts	1990-1994
Undergraduate	Bachelor of Science in Biology University of Washington and Seattle CC Seattle, Washington	1985-1990
	Japanese Language and Literature Aoyama Academy Tokyo, Japan	1982-1985

i. SERVICE

I. Academic:

2015 -- Vice Chair Gynecological subspecialties, Inova Fairfax Hospital
2014 – Professor, Obstetrics and Gynecology, VCU, GWU
2014 -- Professor, Cell Biology, OUHSC
2002 – 2013 Assistant and subsequently Associate Professor and Chief, Section of Female Pelvic Medicine & Reconstructive Surgery/Urogynecology, Oklahoma's first fellowship-trained physician in FPMRS, The University of Oklahoma Health Sciences Center, Department of Obstetrics & Gynecology

As the division director, I established a new division with a 12 year development plan to sequentially mature three programs:

1- Clinical Services

My role at Inova is to provide and coordinate gynecologic programs at the Inova Fairfax Hospital and across the system to serve our patient population. 2015-

Inova academic compensation subcommittee 2015-
Inova competency committee 2015-

Prior to joining Inova, I spent 13 years establishing "**OU Women's Pelvic & Bladder Health Center**" starting at 2002. Since then, this entity has grown to include seven multidisciplinary clinics that bring together the expertise of the best specialists in Oklahoma.

Clinic awards:

- Excel Awards: 2008, 2009, 2010, 2011 (Not given 2012-14), 2015
- 2010 National Health care week 10-17 to 10-23 1st place- Tracking/Testing UTI's
- 2011 National Health care week 10-16 to 10-22 2nd place- Press Ganey-Information about delays
- 2008 National Health care week 10-19 to 10-25 1st place-Tracking and Treating UTI's

"**Women's Surgical Units**" at the OU Medical Center to deliver women a more personalized surgical care.
"**The Pelvic Floor Laboratory**" at the OU Physicians. This clinical laboratory offers the state of the art testing and we believe it is the best in the nation.
"**Oklahoma Pelvic Floor Network (OKPFN)**" as an educational resource to rural physicians and physical therapists.
"**OU Health Care for Executive Women**" a specialized pay for service program for busy executive leaders in Oklahoma.

2- Clinical and Basic Science Research

- My role at Inova is to coordinate gynecologic research programs at the Inova Fairfax Hospital and across the system to serve our patient population.

Prior to joining Inova, I spent 13 years establishing "**The Pelvic Floor Research Laboratory**" at the OUHSC. Secured dedicated research space that is used for pelvic floor studies. We have become known nationally for our readiness to perform clinical trials. We have dedicated research nurses at the Women's Health Center to achieve this end.

● I have collaborated extensively with various basic scientists around OUHSC campus, in particular with Pharmacology department to investigate the pathophysiology of muscle degeneration in pelvic floor disorders.

● I created the "**OU Pelvic Medicine Fund**" to be used for resident and fellow's unfunded research.

3- Educational Programs for Medical Students, Residents, and Fellows

● I am a Professor of Cell Biology and Anatomy due to my expertise in pelvic floor Anatomy. Initially, in addition to being involved with the problem based learning courses, I proctored medical students during abdominal and pelvic dissection. Between 2007-15, I have also given the clinical correlation lecture in Pelvic floor anatomy to the first year medical students.

● I created a suturing and knot tying module that I have handed off to a junior faculty.

- I have established educational programs for Obstetrics and Gynecology residents.
- I led creation of an ACGME accredited fellowship program in FPMRS at OUHSC in 2008.
- I created an on-line anatomy module for the 3rd year medical students rotating through OBG rotation at OU.
- I created a 4th year medical student research and clinical rotation in FPMRS.
- I have provided the leadership training courses to all rotating medical students during their third year OBG rotations.

II. Administrative:

2015— **Vice Chair**, Gynecologic subspecialties, Inova Fairfax Hospital, Falls Church, VA

2002-2015, **Division Chief**,
Female Pelvic Medicine and Reconstructive Surgery (FPMRS). The University of Oklahoma Health Sciences Center, Department of Obstetrics & Gynecology, Oklahoma City, OK

- I brought clinical and basic research in FPMRS to Oklahoma. I have been prolific in national and international meetings, and my number of publications has increased as a result of my ground breaking research in the area of 3D pelvic floor ultrasonography and levator ani anatomy.

- I created an educational curriculum for the Obstetrics and Gynecology residents and medical students.

- FPMRS fellowship achieved ACGME accreditation in January 2013.

- FPMRS achieved the **Center of Excellence** designation by the National Association For Continence (NAFC) in January 2013. The first in the Midwest and one of only 7 elite groups in the United States to achieve the Center of Excellence designation.

2002-2015, **Medical Director**,
OU Women's Pelvic & Bladder Health National Center of Excellence;
Continence Care

- I have directed the growth of this entity from one physician and one nurse to a core group of 30 faculty, staff and research members with extensive interaction with the other clinical services including but not limited to radiology, neurology, urology, colorectal surgery, and sonography.

Past experiences:

2002-15 Section chief, FPMRS, The University of Oklahoma HSC.
Created award winning programs in research, education, and clinical care over a 13 year period.

1988-1991 President
USM Company, Bellevue, WA

- I created and managed a multi-million dollar start-up corporation focusing on exports to Japan. I traveled extensively domestically and internationally for product selection, purchasing and securing contracts. I managed a team of independent contractors to finalize shipping and delivery.

1985 – 1988 Japanese interpreter and fleet maintenance manager
Arctic Ice Fisheries Corporation
Seattle, Washington.

- I built relationships between the Japanese and American deep-sea trawler captains in the Bering Sea and the Gulf of Alaska. I managed staff of 100+ to maintain fleet of 15 deep-sea trawlers.

1982 – 1985 Vice President, Marketing and Design
Japan AMA Corporation
Tokyo, Japan.

- I co-owned and managed a start-up corporation. Conformed to the international clients' needs to design consumer specific sports and casual clothing for export from Japan to Europe, Middle East and the United States.

III. Professional achievements

Oklahoma's first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery / UROGYN 2002-15

Created a new section within the department of Ob/Gyn with a clinical operation that has grown to four fellowship trained physicians, Physician assistants, nurses, support staff, and research support 2002-15

Created Women's Pelvic & Bladder Health brand at the OU Physicians 2002-15

Created the Pelvic Floor Research Laboratory at OU 2002-15

Brought many multi-center clinical trials to OU, as well as other funding for original research 2002-

Created a syllabus and an educational course for OKC and Tulsa residents 2004-

Created an Anatomy workshop and an online anatomy module for MSIII and MS IV students in 2008

Created a suturing workshop and an online suturing course for MSIII and MS IV students in 2008

Created an MS IV elective in FPMRS 2008

Created OU WISH (Women's Incontinence and Sexual Health) support group in 2009

FPMRS fellowship program became accredited by ABOG/ABU 2009

Created Pelvic Floor Investigation Group (PFIG) 2009

Created International 3D Ultrasound Pelvic Floor Imaging Conference and workshops at OU 2010

Became an international research fellowship site for the IUGA and the ICS in 2010, with research scholars from Canada, India, Iran, Thailand, Mexico, Philippines, Europe and the US 2010

GYN Operating rooms transition leadership 2011

OUMC Six Sigma Committee 2011-2012

Created "Oklahoma Pelvic Floor Network" in 2012 as a gathering place for NP, PAs, FPs and PTs to learn about pelvic floor disorders 2012

OU LCME Review Committee 2012

Our FPMRS fellowship achieved ACGME accreditation January 2013

Our group achieved the National Center of Excellence designation by National Association for Continence, January 2013

Created UROGYN Process Improvement Working Group 2013-15

OU Admissions committee 2013-15

OU Dept of Ob/Gyn Co-Chair promotions committee 2014-15

OU Leadership Development Institute Group leader 2014-15

TUFTS-Brandeis University executive management scholarship 2016-17

IV. Community service

Boston Healthcare for the Homeless 1992-1994

Board of Directors, CASA, Oklahoma City	2007-8
Oklahoma City Food Bank	2002-15
OUHSC rowing team	2015

ii. SCHOLARSHIP

I. Publications

NCBI MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1ZO6yTy06z8k0/bibliography/47352728/public/?sort=date&direction=ascending

Published or in publication

1. Rostaminia G, Pickett S, Machiorlatti M, **Shobeiri SA**, Nihira MA. Surgical preference for surgical treatment of stress urinary incontinence among urogynecologic surgeons, comparison after 15 years. Pelviperineology 2015 34(3):75-78.

2. Javadian P, Wendelken J, Quiroz LH, **Shobeiri SA**. Surgical Care Processing in Major Oklahoma City Hospitals: The Surgeons` Perspective. In publication OSMA J.

3. Javadian P, O'Leary D, Rostaminia G, North J, Wagner J, Quiroz LH, **Shobeiri SA**. *How does 3D endovaginal ultrasound compare to magnetic resonance imaging in the evaluation of levator ani anatomy?* In publication nreurourol urodyn

4. Rostaminia G, Peck J, Quiroz LH, **Shobeiri SA.** *Risk factors associated with pelvic organ prolapse in women with significant levator ani muscle deficiency*. In publication IUGJ

5. Towner RA, Wisniewski AB, Wu DH, Van Gordon SB, Smith N, North JC, McElhaney R, Aston CE, **Shobeiri SA**, Kropp BP, Greenwood-Van Meerveld B, Hurst RE. *A Feasibility Study to Determine whether Clinical Contrast-Enhanced MRI can Detect Increased Bladder Permeability in Patients with Interstitial Cystitis.* J Urol. 2015 Aug 22. pii: S0022-5347(15)04676-5. doi: 10.1016/j.juro.2015.08.077. [Epub ahead of print] PMID: 26307161

6. Yune JJ, Quiroz L, Nihira MA, Siddighi S, O'Leary DE, Santiago A, Shobeiri SA. *The Location and Distribution of Transurethral Bulking Agent: 3-Dimensional Ultrasound Study*. Female Pelvic Med Reconstr Surg. 2015 Oct 29. [Epub ahead of print], PMID: 26516814

7. Rostaminia G, Peck JD, Quiroz LH, **Shobeiri** SA. *Characteristics associated with pelvic organ prolapse in women with significant levator ani muscle deficiency.* Int Urogynecol J. 2015 Sep 5. [Epub ahead of print] PMID: 26342811

8. Santoro GA, **Shobeiri SA**, Wieczorek P. *Perineal body anatomy as seen in 3D endovaginal ultrasound of asymptomatic nulliparas*. Colorectal disease 2015 Sep 18. doi: 10.1111/codi.13119. [Epub ahead of print] PMID: 26382090

9. Rostaminia G, Peck J, Quiroz LH, **Shobeiri SA.** *Variability of pubic arch architecture and its role on minimal levator hiatus area*. In Publication, Int J of Gyn Obstet.

10. Pickett S, Barenberg B, Quiroz LH, **Shobeiri SA**, O'Leary D. *The significant morbidity of removing pelvic mesh from multiple vaginal compartments.* Obstet Gynecol 2015 Jun;125(6):1418-22. doi: 10.1097/AOG.0000000000000870. PMID: 26000513

11. Rostaminia G, Peck J, Quiroz LH, **Shobeiri SA.** *Levator Plate Upward Lift on Dynamic Sonography and Levator Muscle Strength.* J Ultrasound Med. 2015 Oct;34(10):1787-92. doi: 10.7863/ultra.15.14.11075. Epub 2015 Sep 2. PMID: 26333568

12. Manonai J, Rostaminia G, Denson L, **Shobeiri SA**. *Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications*. NeuroUrol2015 Jan 25. doi: 10.1002/nau.22725. [Epub ahead of print] PMID:25620321

13. Santiago AC, O'Leary D, Quiroz LH. **Shobeiri SA**. *An Ultrasound approach to the posterior compartment and anorectal dysfunction.* Int Urogynecol J. 2015 Sep;26(9):1393-4. doi: 10.1007/s00192-015-2669-x. Epub 2015 Mar 24. PMID:25800901

14. Santiago AC, O'Leary D, Rostaminia G, Quiroz LH. **Shobeiri SA**. *Is there a correlation between levator ani and urethral sphincter complex status on 3D ultrasound?* Int Urogynecol J 2015;26:699-705 DOI: 10.1007/s00192-014-2577-5 PMID:25448493

15. O'Leary DE, Rostaminia G, Quiroz LH, **Shobeiri SA**. *Sonographic Predictors of Obstructive Defecatory Dysfunction.* Int Urogynecol J. 2015;26:415-20, PMID: 25315168

16. Rostaminia G, White DE, Quiroz LH, **Shobeiri SA**. *How well can levator ani muscle morphology on 3D pelvic floor ultrasound predict the levator ani muscle function?* IUGJ. Int Urogynecol J (2015) 26:257–262. DOI: 10.1007/s00192-014-2503-x. 2014 Sep 23. PMID:25246297

17. Santiago AC, **Shobeiri SA**. *The use of Ultrasound Imaging in Pelvic Organ Prolapse: An Overview.* Current Obstetrics and Gynecology Reports. DOI: 10.1007/s13669-015-0117-z

18. White D, Rostaminia G, Quiroz LH, **Shobeiri SA**. *The Influence of Age on the visualization of the Structures within the Anterior and Posterior Pelvic Floor Compartments.* In publication: Pelviperineology.

19. **Shobeiri SA**, Santiago AC. *Individualized pelvic floor muscle training is an effective conservative treatment in women with pelvic organ prolapse*. Evid Based Med. 2014 Jul 18. pii: ebmed-2014-110020. doi: 10.1136/ebmed-2014-110020. [Epub ahead of print] PMID: 25038067

20. O'Leary DE, Pickett S, **Shobeiri SA**. *Description of the methodology in the study of the association between vaginal parity and minimal levator hiatus.* BJOG DOI: 10.1111/1471-0528.12958 PMID: 24990183

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23. Van Delft K, **Shobeiri SA**, Thakar R, Schwertner-Tiepelmann N, Sultan AH. Reply: *Inter-rater and Intra-rater reliability of levator ani muscle biometry and detachment using three dimensional endovaginal ultrasonography.* Ultrasound Obstet Gynecol. 2014 Apr;43(4):480.

doi: 10.1002/uog.13329 PMID: 24692223

24. Allen AM, **Shobeiri SA,** Quiroz LH, Fong DN, Nihira MA. Obstetric Laceration Repair in the United States: Is there a Common Practice? JRM 2014 59:127-133 PMID: 24724220.

25. Nihira MA, Quiroz LH, Hardre P, **Shobeiri SA.** *Training Community Gynecologists to Perform Intraoperative Cystoscopy: A Competency-Based Training Experience*. FPMRS 2014;20(2):76-82. doi: 10.1097/SPV.0000000000000056. PMID: 24566209

26. Denson LE, **Shobeiri SA**. *3 Dimensional Endovaginal Ultrasound Imaging of Synthetic Implanted Materials in the Female Pelvic Floor*. *JUM March 2014 33:521-529. doi:10.7863/ultra.33.3.521 PMID:24567464*

27. Denson LE, **Shobeiri SA**. *Peroxide-enhanced 3-dimensional endovaginal ultrasound imaging for diagnosis of rectovaginal fistula.* Female Pelvic Med Reconstr Surg. 2014 Jul-Aug;20(4):240-2. doi: 10.1097/SPV.0000000000000074. PMID: 24978092

28. Smith TA, Poteat TA, **Shobeiri SA**. *Pelvic Organ Prolapse; A Review*. JAAPA. 2014;27(3):20-24. DOI: 10.1097/01.JAA.0000443963.00740.4d PMID: 24500120

29. Rostaminia G, Omoumi F, **Shobeiri SA**. *Statistical justifications for interrater reliability of levator ani deficiency (LAD) assessment by 3D endovaginal ultrasonography: response to critique*, DOI: 10.1007/s00192-014-2351-8 PMID: 24497093

30. Rostaminia G, White D, Quiroz LH, **Shobeiri SA.** *Freehand Acquisition of 3D Transperineal Pelvic Floor Volume Does not yield accurate measurements*. Pelviperineology. 2013;32:99-103.

31. Rostaminia G, Manonai J, LeClaire E, White D, Marchiorlatti M, Quiroz LH, **Shobeiri SA**. *Interrater reliability of assessing levator ani deficiency with 360 Degree 3D Endovaginal Ultrasound*. 2014 Jun;25(6):761-6. IUGJ, DOI. 10.1007/s00192-013-2286-5. PMID: 24337615

32. Rostaminia G, Manonai J, LeClaire E, White D, Quiroz LH, **Shobeiri SA**. Erratum to: *Interrater reliability of assessing levator ani deficiency with 360 Degree 3D Endovaginal Ultrasound*. Int Urogynecol J. 2014 May;25(5):623-9. PMID: 24497093

33. Van Delft K, **Shobeiri SA**, Schwertner-Tiepelmann N, Thakar R, Sultan AH. *Inter-rater and Intra-rater reliability of levator ani muscle biometry and detachment using three dimensional endovaginal ultrasonography. USOG* 2014 Feb;43(2):202-9*;* DOI: 10.1002/uog.13193. PMID: 23939804

34. Rostaminia G, White D, Quiroz LH, **Shobeiri SA**. *3D Pelvic Floor Ultrasound Findings and Severity of Anal Incontinence. IUGJ* DOI: 10.1007/s00192-013-2278-5 PMID: 24310989

35. Denson LE, **Shobeiri SA**. *Ultrasound Imaging of Urethral Bulking Materials; A Sonographer's prespective*. J diagnostic Med Sonography. Published online before print October 7, 2013, doi: 10.1177/8756479313506785.

36. Rostaminia G, White DE, Quiroz LH, **Shobeiri SA**. *Levator Plate Descent Correlates with Levator Muscle Deficiency*. Neurourol Urodyn DOI: 10.1002/nau.22509 PMID 24132730

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Submissions

98. Shobeiri SA. Lean-Six sigma; A Center of Excellence Experience. In progress.

99. Shobeiri SA. Aligning medical students with academic institution goals. In Progress.

100. Shobeiri SA, White DE, Rostaminia G. 5 year review of a successful international ultrasound workshop. In progress.

101. Javadian P, Shobeiri SA. 10 year review of an anal sphincter repair workshop for Obstetrics and Gynecology residents. In progress.

102. Meyer I, Quiroz LH, **Shobeiri SA**. *Intraoperative suprapubic pressure test for prevention of de novo stress urinary incontinence after correction of pelvic organ prolapse.* Submitted.

103. Meyer I, Quiroz LH, Nihira MN, **Shobeiri SA**. *Medium to long-term outcomes of the anterior Hammock procedure using autologous fascia lata*. Submitted.

104. **Shobeiri SA**, Quiroz LH, Santoro GA et al. *Pelvic Floor Phantoms: A Step Forward in Teaching Hands-on Pelvic Floor Sonography to a Large Group of Participants*. Submitted.

105. Manonai J, Shobeiri SA. Levator plate architecture and anal complex in women with or without fecal incontinence. In progress.

106. Shobeiri SA. Relative contributions of the levator ani subdivisions to levator ani movement. In progress.

107. Rostaminia G, Quiroz LH, Shobeiri SA. Levator ani muscle deficiency and the influence of age and parity. Submitted

108. Javadian P, Shobeiri SA. Ultrasonic predictors of mesh complications. In progress.

109. Javadian P, Shobeiri SA. Trans-obturator tape syndrome: Ultrasonic Predictors of Pain. In progress.

110. Javadian P, Shobeiri SA. Comparison of in-person vs internet based Anatomy module for third year medical students. In progress.

111. Javadian P, Shobeiri SA. Public Health Impact of Vaginal Mesh Complications on Women's Health. In progress.

II. Books and book chapters

Ambulatory Urology and Urogynecology 2017

Editor: Ajay Rane, MD, Wiley Publishers 2017

- Pelvic floor Anatomy, **Shobeiri SA**
- Pelvic floor trauma, Rostaminia G, **Shobeiri SA**
- Pelvic floor ultrasound, Denson LE, **Shobeiri SA**
- Injection Therapy for stress urinary incontinence, **Fatehchehr S, Shobeiri SA**
- Classification of Meshes, Stone D, **Shobeiri SA**
- Anatomy of Female Urethra, Santiago A, **Shobeiri SA**

Childbirth Trauma 2017

Editor: Stergios Doumouchtsis,
Springer publishers, in publication 2016.

- Epidemiology of Childbirth Trauma
Lieschen H. Quiroz, and **S. A. Shobeiri**
- Ultrasonography of Childbirth Trauma
Ghazaleh Rostaminia, and **S. A. Shobeiri**

Practical Pelvic Floor Ultrasonography (2nd Edition)

Editor: S. Abbas Shobeiri, Springers Publishers 2017

- Endovaginal Ultrasonography, **Shobeiri SA**

Anorectal and Pelvic Floor Ultrasonography

Editor: Lucia Oliveira and Sthela Regadas, Wiley Publishers 2016

- Endovaginal Ultrasonography, **Shobeiri SA**

Seminars in Colon and Rectal Surgery

Editor: Anders Mellgren, Wiley Publishers 2016

- Management of Pelvic pain, Javadian P, **Shobeiri SA**

Current Obstetrics and Gynecology 2015

Section Editor, **Shobeiri SA**.

- Review of Pelvic floor trauma and its relationship to Pelvic Organ Prolapse,
Benjamin Barenberg and Lieschen H. Quiroz
- Review of Vaginal Mesh complications in Pelvic Organ Prolapse surgeries,

Pouya Javadian and Dena O'Leary
- ❖ Review of Uterine morcellation use in Pelvic Organ Prolapse surgeries, Soorena Fatehcher and Ceana Nezhat
- ❖ Review of Pelvic floor ultrasound imaging in Pelvic Organ Prolapse, Andrea Santiago and **SA Shobeiri**
- ❖ Review of Advances in surgical treatment of Fecal Incontinence, Isuzu Meyer and Holly Richter
- ❖ Review of 3D Modelling and Pelvic Organ Prolapse, Ghazaleh Rostaminia and Steven Abramovitch

Principles and Practice of Urogynaecology 2015

Editors: Arjunan Tamilselvi & Ajay Rane
2015, XIV, 178 p. 77 illus., 61 illus. in color.
Springer India, Publication 2015, pp 17-22,
ISBN 978-81-322-1692-6, DOI 10.1007/978-81-322-1692-6_2,
- ❖ Neuroanatomy of the Female Pelvis, Pickett S, **Shobeiri SA**.

Practical Pelvic Floor Ultrasonography 2015

Editor: **S. A. Shobeiri**,
Springer publishers, 2014.
237 p. 302 illus., 261 illus. in color.
ISBN: 978-1-4614-8425-7
(Print) 978-1-4614-8426-4 (Online),
DOI 10.1007/978-1-4614-8426-4
- ❖ Introduction
S. Abbas Shobeiri
- ❖ Pelvic Floor Anatomy
S. Abbas Shobeiri
- ❖ 2D / 3D Endovaginal & Endoanal Instrumentation and techniques
S. Abbas Shobeiri
- ❖ Instrumentations and Techniques for Transperineal and Translabial Pelvic Floor Ultrasound
Milena Weinstein & **S. Abbas Shobeiri**
- ❖ 3D Endovaginal Ultrasound Imaging of the Levator Ani Muscles
Lieschen H. Quiroz & **S. Abbas Shobeiri**
- ❖ Endovaginal Imaging of the Urethra and the Bladder
A. Pawel Wieczorek & Magdelena M. Wozniak
- ❖ Endovaginal Imaging of the anorectal structures
Dena White & **S. Abbas Shobeiri**
- ❖ Endovaginal Imaging of Vaginal implants
Aparna Hegde & G. Willy Davila
- ❖ Endovaginal Imaging of Pelvic Floor Cysts and Masses
Ghazaleh Rostaminia & **S. Abbas Shobeiri**
- ❖ Endoanal Ultrasonography of the Anorectal Region
Giulio A. Santoro & Sthela Murad-Regadas
- ❖ Endoanal Ultrasonography of the Anorectal Cysts and Masses
Sthela Murad-Regadas & Giulio A. Santoro
- ❖ Emerging Pelvic Floor Technologies and Techniques
S. Abbas Shobeiri & Jittima Manonai
- ❖ Post-Test on Pelvic Floor Imaging
S. Abbas Shobeiri

International Academy of Pelvic Surgery 2011

Walters, M., Karram, M. Eds. Online Publication: June, 2011

❖ Simulation and Gynecologic Surgery: *A Complementary Teaching Approach to the "See One, Do One, Teach One" Method for Surgical Training*.
Nihira, MA and **Shobeiri, SA**.

Pelvic Floor Disorders 2010

Editor: Giulio A. Santoro, MD, PhD and Pawel Wieczorek, MD
Springer publishers, October 14, 2010 | ISBN-10: 8847015413 | ISBN-13: 978-8847015418 | Edition: 2010

❖ *Advances in our understanding of pelvic floor anatomy*. PP 3-16
John O. DeLancey and **S. A. Shobeiri, MD**.

❖ *Endovaginal three Dimensional Sonography*. PP 61-78
Giulio Santoro, MD, Pawel Wieczorek, MD, and **S. A. Shobeiri, MD**.

❖ *Imaging Complications of Urogynecological Surgery in a New Age*. PP 695-710
S. A. Shobeiri, MD.

Muscular System - Anatomy, Functions and Injuries 2008

❖ *Anal sphincter damage and childbirth mechanism of action, diagnosis and treatment.*
NOVA publishers,
ISBN: 978-1-62100- 2010, *PP 190-4*
Francesca Sartori, Giulio Santoro, **S. A. Shobeiri**.

Atlas of the Urologic Clinics of North America 2003

❖ *Uterosacral Suspension of the Vaginal Vault*.
Volume 11, Issue 1, Pages 113-127, April 2003 PP *113-117.*
R. R. Chesson, MD, **S. A. Shobeiri, MD**.

iii. FUNDING

I. Local

Negotiated funding for OU Women's and Pelvic Bladder Health Center
Negotiated creation of Women's surgical suites at OU Medical Center
Created OU Women's Pelvic Medicine Fund
Negotiated funding for faculty and fellows
Raised funds after a friend died of Melanoma to dedicate a conference room at the OU cancer center to her name.

II. Research funding pending

NIH NICHD (Submitted) Pelvic Floor Disorders Network Clinical Sites
PI
2016-2021 15% effort

NIH NICHD R21 (Submitted) Structural and Inflammatory Basis of Levator Ani Regeneration
PI
2016-2018 20% effort

III. Funded Research

VTI Phase IV Research
NIA

PI: Vladimir Egorov, PhD, Artann Laboratories Inc.

NIH NICHD 1U01HD077384-01A1: Optimizing Management of the 2nd Stage (OMSS): a Multicenter Trial
Consultant / Co-investigator, PI: Alison Cahill, MD, Washington University
2014-2018 10% effort

The TRUST study (Treatment Results of Uterine Sparing Technologies) U.S.A. Study"
Halt Medical Inc. $383,910.00
PI
07/06/2015 – 05/31/2016 5% effort

NIH NIAID Cooperative Centers for Research in Human Immunology Program grant number U19AI062629 Innate Immune Response upon West Nile Virus Infection of Human Skin
Co-investigator, PI: Jose Alberola, PhD (OU). Mark Coggeshall, PhD (Stanford)
2015-2016 3% effort

NIH NIDDK 5P20DK097799-02: The Role of Altered Permeability in Bladder Diseases
Co-investigator, PI: Robert Hurst, PhD
2014-2015 5% effort

NIH NIAID U19 AI6262: Development of a human skin explant model for modeling cutaneous bacterial infection
Co-investigator, PI: Susan Kovats, PhD
2014-2015 5% effort

ACELL Study
Randomized multicenter trial of Matristem vs. native tissue repair
Co-investigator
2014- 5% effort

International Urogynecologic Association (IUGA) 2013 research scholar award
Andrea Santiago, MD, Philippines

International Continence Society (ICS) 2013 Research Scholar award
Jittima Manonai, MD, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand

American Urogynecologic Society (AUGS Foundation grant)
"The greatest risks of obstetrics trauma during childbirth"
Co-investigator
2012-2014, 5% effort

(ACOG) American College of Obstetricians and Gynecologists Kenneth Gottsfield-Charles Hohler Memorial Foundation Research Award in Ultrasound
"Effects of childbirth on the pelvic floor of women"
Co-investigator
2012-2014, 5% effort

AUGS 2011 Thomas Benson award
"Findings at Peripheral Nerve Evaluation: What is the significance of levator ani muscle status?"
2012-Present, 5% effort

OU Clinical and Translational Sciences Scholar Program 2011
Melissa Muhlinghouse,

AUGS 2010 Thomas Benson award
"Vaginal Electrical Stimulation vs. Sacral Neuromodulation for the Treatment of Refractory Overactive Bladder: A Pilot Study"
2011-Present, 5% effort

TRANSFORM Study
"An investigation of the TReatment of Fecal Incontinence Using the TOPAS Sling System For WoMen (TRANSFORM)"
4/2010-2013

OU Clinical and Translational Sciences Scholar Program 2010
Jordan Brady,

BK Medical Inc. PI,
Histological correlative study of Pelvic floor to 3D Ultrasonography

OU College of Medicine Alumni Foundation Grant
Effect of aging on the levator ani muscles
Co-investigator

Uroplasty, Inc.
Study of Urgent PC Versus Sham Effectiveness in Treatment of Overactive Bladder Symptoms.
A Multicenter trial
Co-investigator
9/10/2008 - 9/9/2011

Uroplasty, Inc.
Macroplastique Real-Time Observation of Safety and Effectiveness in the Treatment of Female Stress Urinary Incontinence - Rose Registry A Multicenter trial
Co-investigator
2/4/2008 – 2/3/14

BK Medical Inc.
3D ultrasonography of pelvic floor muscles
Principle Investigator

Uroplasty Inc.
Detrol vs. pretibial nerve stimulation trial. A Multicenter trial
Co-investigator

U.S. Surgical
Evaluation of posterior intravaginal slingplasty. A Multicenter trial
Co-investigator

Interstim Bowel Control: Fecal Incontinence Study
A Multicenter trial
Co-investigator
2003

National Institute of Health Loan Repayment Program
2003-2005

American Medical Systems
Trial of BioArch anti-incontinence device. A Multicenter trial
Co-investigator

2003

Neotonus Inc.
Magnetic Resonance Imaging of the Levator Ani Muscles
Principle Investigator
2001

iv. TEACHING

I. Presentations

1) International

European Pelvic Floor Therapy Symposium: Keynote speaker
Pelviusse-Symposium
Winterthur, Switzerland,
November, 14, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Montreal, Canada
October, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Niece, France
June, 2015

How to create an award winning pelvic floor center, round table presentation
International Urogynecological Association
Niece, France
June, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Rio, Brazil
October, 2014

Posterior Compartment Dysfunction Workshop: Presenter
International Continence Society
Rio, Brazil
October, 2014

Recognition and management of Obstetric fistulas: Presenter
International Continence Society
Rio, Brazil
October, 2014

IUGA/AUGS Scientific Meeting
How to create an award winning pelvic floor center, round table presentation
Washington DC, USA
July, 2014

IUGA/AUGS Scientific Meeting
Pelvic floor repair using autologous harvest, round table presentation
Washington DC, USA
July, 2014

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Washington DC, USA
July, 2014

Posterior Compartment Dysfunction Workshop: Presenter
International Urogynecological Association
Washington DC, USA
July, 2014

Fistulas in developing and developed countries: Presenter
International Urogynecological Association
Washington DC, USA
July, 2014

IUGA Regional Conference,
International Urogynecological Association
Pubococcygeal avulsion, Myth or reality
Quality of life Inventories in urogynecology which ones to use
Defecatory dysfunction
Conventional imaging in pelvic floor disorders
Bogata, Columbia
February 2014

IUGA Regional Conference, Featured Speaker
International Urogynecological Association
Management of Mesh Complications
Role of Transperineal and Endoanal Ultrasound
OAB: Approach and Management
Hyderabad, India
November 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Barcelona, Spain
September 2013

Posterior Compartment Dysfunction Workshop: Presenter
International Continence Society
Barcelona, Spain
September 2013

Recognition and management of Obstetric fistulas: Presenter
International Continence Society
Barcelona, Spain
September 2013

Frontiers of Pelvic Floor Imaging: Featured Speaker
Comprehensive 3D Ultrasound imaging of pelvic floor workshop
State of the art pelvic floor imaging
Round table discussion: Levator ani repair

Mexican Urogynecologic Society Meeting
Mexico City, Mexico
June 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Dublin, Ireland
May 2013

Posterior Compartment Dysfunction Workshop: Presenter
International Urogynecological Association
Dublin, Ireland
May 2013

Recognition and management of Obstetric fistulas: Presenter
International Urogynecological Association
Dublin, Ireland
May 2013

Advances in Pelvic Floor Imaging, What Does It Mean? Featured Speaker and panel discussion
56th All India Congress of Obstetrics and Gynecology
Mumbai, India
January 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Posterior Compartment Dysfunction workshop: Speaker
International Continence Society
Beijing, China
October 2012

Frontiers of Ultrasound Pelvic Floor Imaging, IUGA Fellows' Forum: Chairman
International Urogynecological Association,
Brisbane, Australia
September 2012

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Brisbane, Australia
September 2012

Pelvic Floor Imaging and Research
Collaborative OU and Croydon University Hospital Research Group
London, England
February 2012

Endoanal Ultrasonography for Ob/Gyn: Featured speaker
Role of Ultrasonography in Pelvic Floor: Featured speaker
Evaluation of Mesh Complications in Pelvic Floor Surgery
International Federation of Gynecology and Obstetrics
FIGO Working Group on Pelvic Floor Medicine and Reconstructive Surgery meeting and The Royal Thai College of Obstetricians and Gynecologists
Bangkok, Thailand
November 2011

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman

International Continence Society,
Glasgow, England
September 2011

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Posterior Compartment Dysfunction
International Urogynecological Association
Lisbon, Portugal
June 2011

Imaging Complications of Urogynecological Surgery: Featured Speaker
50th FOCUS in Obstetrics and Gynecology
Hong Kong
June 2011

Advanced Pelvic Floor Imaging,: Featured Speaker
Hong Kong Urogynecological Association Meeting
Hong Kong
June 2011

State of the Art Pelvic Floor Imaging: Featured Speaker
Controversies in Ob/Gyn: Why Doesn't Mesh Always Work
Controversies in Ob/Gyn: Anatomy and Function of the Anal Sphincter
Annual clinical meeting of ACOG
Mexico City, Mexico
June 2011

Anatomy of the Anterior Compartment
American Society of Colorectal Surgeons
Vancouver, Canada
May 2011

Surgical Interventions for Pelvic Organ Prolapse
Advanced Pelvic Floor Anatomy and Ultrasound Imaging
Treviso Ultrasound Symposium
Treviso, Italy
November 2010

Case studies in 3D Ultrasound Pelvic Floor Imaging
BK Symposium
Copenhagen, Denmark
November 2010

State of the Art Pelvic Floor Imaging
Spanish Hospital
Mexico City, Mexico
October 2010

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Toronto, Canada
August 2010

Ultrasound Imaging of Pelvic Floor Anatomy
Ultrasound Symposium
Krakow, Poland

June 2010

Imaging Complications of Urogynecological Surgery: Featured Speaker
12th annual Japanese Pelvic Medicine Society
Omiya, Japan
May 2010

Pelvic Floor Anatomy
Hacettepe University Medical Center
Ankara, Turkey
March 2004

The Anatomy and Function of the Female Genitourinary Tract
Saitama University, Department of Obstetrics & Gynecology
Saitama, Japan
August 2001

2) National

Pelvic Floor Disorders week
Practical aspects of pelvic floor ultrasonography, Ultrasound workshop
American Urogynecological society
Seattle, WA
October 2015

Pelvic Floor Disorders week
How to incorporate Ultrasonography into your practice
American Urogynecological society
Seattle, WA
October 2015

Pelvic Floor Ultrasound
Seattle Gynecological Society
Seattle, WA
September 2015

Management of mesh complications
Seattle Gynecological Society
Seattle, WA
September 2015

2D and 3D Multicompartmental Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Society of Gynecological Surgeons' Annual Meeting
Hollywood, Florida
March, 2015

Transperineal vs endovaginal 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman, Co-Chair: Phyllis Glanc, MD, Associate Professor of Radiology, The University of Toronto
American Institute of Ultrasound in Medicine Annual Meeting
Hollywood, Florida
March, 2015

Pharmacologic Treatments for Urogynecologic Conditions
Inova Fairfax Hospital, Virginia
February, 2015

Regional Professional Coders Association
Business Aspects of running a continence program
Oklahoma City, OK
November, 2014

The University of North Carolina
Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Durham, NC
December, 2013

Imaging of Pelvic Floor Disorders, Session Moderator
American Urogynecologic Society
Chicago, IL
September 2012

Incorporating 3D Ultrasound imaging into your practice, round tables
Intraoperative 3D Ultrasound imaging of pelvic floor, Fellows' lecture series
American Urogynecologic Society
Providence, Rhode Island
September 2011

Advanced Pelvic Floor Imaging
Cleveland clinic Ultrasound Imaging symposium
Cleveland Clinic, FL
March 2011

3D Ultrasound Imaging of Pelvic Floor Workshop
73rd annual University of Minnesota Colorectal Surgery
Minneapolis, MN
October 2010

3D Ultrasound Imaging of Pelvic Floor – One Day Workshop: Chairman
International Continence Society
San Francisco, CA
May 2009

Pelvic Floor Dysfunction and the Use of Botox
Seattle Gynecological Society
Seattle, WA
September 2006

How to Prepare a Poster Presentation
American Urogynecological Society Fellows' Research Retreat
April 2006

How to Build Specific Aims and Hypothesis
American Urogynecological Society Fellows' Research Retreat
April 2006

The Anatomy of the Female Bladder and the Urethra
Baylor University Medical Center
Dallas, TX
June 2001

Female Pelvic Medicine…What is it?

Tulane University School of Medicine
New Orleans, LA
May 2001

The Overactive Bladder, Advancements and Disappointments
Louisiana State University Health Sciences Center
New Orleans, LA
June 2000

Preoperative, Intraoperative & Postoperative Complications
New Orleans Ob/Gyn Board Review course
2000, 2001, 2002

Adnexal Masses,
New Orleans Ob/Gyn Board Review course
May 2000

Hysterectomy
New Orleans Ob/Gyn Board Review course
May 2000

Anatomy Course Proctor
American Urogynecological Society
New Orleans, LA
March 2000, April 2001, April 2003

Pelvic Anatomy Lab Proctor
Second year Anatomy course
Louisiana State University Medical School
1999, 2000

Chronic Pelvic Pain
Grand Rounds
Louisiana State University Health Sciences Center
April 1999

3) Regional

Inova Leadership Development Institute
Falls Church, VA
November 2015

OU Leadership Development Institute
Surgical Care NOS, Round table facilitator
Oklahoma City, Oklahoma
February 2014

Pelvic Floor Dysfunction
Tulsa Ob/Gyn Society
Tulsa, Oklahoma
September 2007

Evidence Based Cystoscopy for Practicing Ob/Gyn
Tulsa Ob/Gyn Society
Tulsa, Oklahoma

July 2005

The Overactive Bladder Syndrome
The American Academy of Family Physicians
Oklahoma City and Tulsa, Oklahoma
February 2005

Female Pelvic Medicine and Reconstructive Surgery
Tulsa Ob/Gyn Society
Tulsa, Oklahoma
February 2005

4) Local

Correlative Gynecologic anatomy
Inova Fairfax resident lecture series
December 2015

Art and Medicine interest group Invited speaker
The University of Oklahoma Health Sciences Center
March 2014

The Painful Bladder Syndrome and the Unseen Etiologies of CPP
The University of Oklahoma Pain Symposium
May 2009

Pudendal Neuropathy
The University of Oklahoma Health Sciences Center Grand rounds
Oklahoma City, Oklahoma
March 2009

Pudendal Neuropathy
Oklahoma City Ob/Gyn Society
Oklahoma City, Oklahoma
August 2008

Peripheral Neuropathy in Gynecologic Surgery
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
May, 2008

Embryologic Basis of Vaginal Agenesis
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
March 2008

The Painful Bladder Syndrome and the Unseen Etiologies of CPP
The University of Oklahoma Pain Symposium
Oklahoma City, OK
March 2007

Urinary Incontinence
The University of Oklahoma Primary Care Conference
Oklahoma City, OK
May 2006

The Unseen Pathologies of the Pelvic Nervous System
MERCY Hospital
Oklahoma City, Oklahoma
March 2006

The Pathophysiology of the Overactive Bladder Syndrome
The University of Oklahoma Family Practice Grand Rounds
Oklahoma City, Oklahoma
May 2005

Physical Therapist's Treatment of the Female Pelvic Floor
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
April 2004

Physical Therapist's Evaluation of the Female Pelvic Floor
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
January 2004

Applied anatomy for Pelvic Floor Rehabilitation
Oklahoma Physical Therapy Association Meeting
October 2003

The Overactive Bladder
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
November 2002

The Unseen Pathologies of the Pelvic Nervous System
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
October 2002

5) Abstract presentations

International

International Continence Society
Barcelona, Spain – 2013

1. Effects of the first vaginal delivery in women early postpartum versus years remote from delivery
2. 3-dimensional endovaginal ultrasound can reliably detect normal anal sphincter anatomy
3. Predictors of anal incontinence in the absence of anal sphincter defect
4. Sonographic predictors of obstructive defecatory dysfunction
5. Relative contributions of the levator ani subdivisions to levator ani movement

37th Annual Meeting of the International Urogynecologic Association
Brisbane, Australia – 2012

1. Comparison of 3D endovaginal ultrasound to magnetic resonance imaging of the pelvic floor musculature
2. How much levator muscle defect is associated with female pelvic organ prolapse?
3. Does the visualization of pelvic floor structures change with age?
4. Borders of the minimal levator hiatus and their relationship to the puborectalis muscle and the levator plate

5. The visualization of urethral muscles is not associated with continence status in patients with prolapse
6. Levator plate angle: a new measure that demonstrates levator plate descent correlates with poor levator muscle status
7. Open versus minimally invasive sacrocolpopexy: a comparison of de novo urinary symptoms

36th Annual Meeting of the International Urogynecologic Association
Glasgow, Scotland – 2011

1. 3D Ultrasound anatomy of the female pelvic floor, a direct histologic comparison: anterior and posterior compartments
2. Age effects on pelvic floor symptoms in a cohort of nulliparous patients

National

41st Annual Society of Gynecology Surgeons Meeting
Orlando, FL – 2015

1. Risk factors of lower urinary tract injury at the time of prolapse and incontinence repair

35th Annual Meeting Society of Maternal-Fetal Medicine
San Diego, CA - 2015

1. Performance of the fasting glucose value alone for diagnosing gestational diabetes and predicting neonatal adiposity

62nd Annual Meeting of the Pacific Coast Reproductive Society
Rancho Mirage, CA – 2014

1. Initiating infertility treatment: does it improve or worsen anxiety and/or depression?
2. The acceptance and donation of fertility medications: examining the frequency and protocols in place across United States fertility clinics
3. Does fertility treatment affect marital satisfaction? A pilot study.

AUGS/IUGA Joint Annual Scientific Meeting
Washington, DC – 2014

1. Complications during mesh removal and patient-based outcomes after mesh removal
2. Decreased urethral volume on 3-D endovaginal ultrasound is comparable to bladder neck funneling on fluoroscopy as a predictor of intrinsic sphincter deficiency
3. Is there a correlation between levator ani deficiency and urethral sphincter complex measurements on 3-D endovaginal ultrasound?
4. Multicompartmental ultrasound approach to anorectal dysfunction

34th American Urogynecologic Society Annual Scientific Meeting
Las Vegas, NV – 2013

1. Are there sonographic predictors of obstructive defecatory symptoms?
2. Can 3-dimensional ultrasound detect normal anal sphincter anatomy?

38th Annual Society of Gynecologic Surgeons Meeting
Baltimore, MD – 2012

1. The influence of obesity on complication rates following benign hysterectomy
2. Outcomes of minimally invasive and abdominal sacrocolpopexy: A Fellows' Pelvic Research Network Study

33rd American Urogynecologic Society Annual Scientific Meeting
Chicago, IL – 2012

1. Interrater reliability of 3D endovaginal ultrasound anatomy of asymptomatic nulliparous women based on direct histologic comparison: anterior and posterior compartments

32nd American Urogynecologic Society Annual Scientific Meeting

Providence, RI – 2011

1. Does the visualization of pelvic floor structures change with age?
2. Incidence of unanticipated uterine pathology at the time of minimally invasive sacrocolpopexy
3. 3D Ultrasound anatomy of the female pelvic floor, a direct histologic comparison: anterior and posterior compartments
4. Age effects on pelvic floor symptoms in a cohort of nulliparous patients

31st American Urogynecologic Society Annual Scientific Meeting (Fellows Forum)
Long Beach, CA – 2010

1. Vaginal mesh complications in the community: the experience of a university-based urogynecology practice

II. Videos and media presentations

Implications of FDA warning on morcellation complications. KWTV Newscast, Oklahoma City 2014
Implications of FDA warning on vaginal mesh kit complications. KWTV Newscast, Oklahoma City 2014
Fascia Lata Hammock Procedure AUGS / IUGA 2014 Barenberg, B. Shobeiri SA,
Posterior Compartment 3D Ultrasound Imaging AUGS / IUGA 2014 Santiago A, Shobeiri SA
Oklahoma Live, KSBI 52, featured local artist, Oklahoma City 2013
Urethral bulking agents KOTV TV Newscast, Oklahoma City 2004
Pudendal Neuralgia KOCO TV Newscast, Oklahoma City 2006
Pelvic pain KOCO TV Newscast, Oklahoma City 2007
Interstim therapy KFOR TV Newscast, Oklahoma City 2003

III. Teaching Materials Developed

2009 -– Present Ultrasound module for ultrasonography students

2014- Working group to develop Anatomy modules for first year medical students

2010 – Present Pelvic Floor Ultrasound Phantom – currently working with an external vender to commercially produce the models

2008 – 2013 Third year Medical student suturing course

2010 – Present Third year Medical student professionalism course / AIDET

2008 – Present Third year Medical student pelvic anatomy course

2006 – Present Workshop for the repair of 3rd and 4th degree Obstetric lacerations

2005 – 2010 Blackboard for teaching Urogynecology

2002 – Present Teaching anatomy to 1st year Medical students

2002 – Present Urogynecology teaching core curriculum

IV. Creative Achievements

1999 - Present I have created new procedures and surgeries for evaluation and treatment of pelvic floor disorders including a collaborative patent development agreement for an ultrasound phantom

2012 BJOG (British Journal of Obstetrics and Gynecology) top Reviewer

2010 APGO Excellence in Teaching Award

2010 AUGS, Best Educational Research Award

2007 – 2013 Medical student teaching awards

1999 Resident Research Award, *Utilization of ultrasonography for the evaluation of anal sphincter repair*

V. Resident Mentees

1. Buchinger, D, Shobeiri, SA. Is cervical dilation a predictor of post-partum urinary incontinence: A comparison of patients undergoing cesarean section versus vaginal delivery? June, 2006.
2. LeClaire E, Shobeiri SA. 3D Anatomy of pelvic Floor Muscles. June 2007.
3. D. Nelson Fong, MD, Advisor: S. Abbas Shobeiri, MD, A Standard Method of Primary Obstetric Anal Sphincter Repair, 2009.
4. D. Nelson Fong, MD, Advisors: S. Abbas Shobeiri, MD; Lieschen Quiroz, MD; Mikio Nihira, MD; Arielle Allen, MD, Obstetric Anal Sphincter Laceration Repair in the United States: Is there a Common Practice Pattern? 2010
5. Isuzu Meyer, M.D., Advisor: S. Abbas Shobeiri, M.D., Determinants of Occult Stress Urinary Incontinence after Correction of Prolapse, 2010
6. Isuzu Meyer, MD PGY 4, Lieschen Quiroz, MD, S. Abbas Shobeiri, MD. Effects of Childbirth on Pelvic Floor Muscle Strength 2012
7. Juarez, Dianna, PGY 4, LeClaire, Edgar L., Quiroz, Lieschen H., Mukati, Marium S., White, Dena, Shobeiri SA, Abdominal *vs*. Minimally-Invasive Sacrocolpopexy: A Comparison of *de novo* Stress Urinary Incontinence Outcomes, 2012
8. Wesley Vaughn, PGY 3, S. Abbas Shobeiri, MD. The psychosocial behavior pattern of the residents and faculty at OUHSC OB/GYN dept. 2014
9. PGY2, 3rd and 4th degree laceration repair training program. Is there a deficit?

VI. Post-doc Mentees

2015- Wang Li, MD, China, FPMRS research scholar
Mentored in conduct of research

2014- Pouya Javadian, MD, Iran, FPMRS research scholar
Mentored in conduct of research, MS thesis: Public Health impact of surgical intervention

2011 – 2014 Ghazaleh Rostaminia, MD, Iran, FPMRS research scholar
Mentored in conduct of research, MS thesis in 3D Finite element modelling, 3D pelvic floor Ultrasonography.

2011 – 2013 Marium Mukati, MD, USA, FPMRS research scholar
Mentored in conduct of research.

March 2013 Joshua Yune, MD, USA, FPMRS fellow, Loma Linda University
Mentored in conduct of research, 3D pelvic floor Ultrasonography.

March 2012 Parifar Rostami, MD, Canada, FPMRS research observer
Mentored in conduct of research.

November 2011 Elena Tunitsky, MD, USA, FPMRS fellow, Cleveland Clinic
Mentored in conduct of 3D pelvic floor Ultrasonography.

2011 - 2013 Kim Van Delft, MD, Denmark, Croydon University, UK fellow
Mentored in conduct of research, PhD thesis in 3D pelvic floor Ultrasonography.

May 2012 Aparna Hegde, MD, India, (IUGA) Research scholar
Mentored in conduct of research in 3D pelvic floor Ultrasonography.

January 2013 Samaneh Sehat Baksh, MD, Iran, Research observer
Mentored in conduct of research.

April – June 2013 Jittima Manonai, MD, Thailand, International Continence Society (ICS) Research scholar
Mentored in conduct of research, 3D pelvic floor Ultrasonography.

2013 - 2015 Andrea Santiago, MD, Philippines, International Urogynecological Association (IUGA) Research scholar
Mentored in conduct of research, 3D pelvic floor Ultrasonography.

2013 - Present Lindsay Denson, RDMS, USA, “MPH” Research Scholar
Mentored in conduct of research, MS thesis in 3D pelvic floor Ultrasonography investigation of pelvic floor injury with vaginal delivery.

2014 - Present Pouya Javadian, MD, Iran, FPMRS research fellow

July - October 2013 Daniel Velez, MD, Mexico, “PhD” FPMRS Research scholar
Mentored in conduct of research, PhD thesis in 3D pelvic floor Ultrasonography and perineal injury associated with vaginal delivery.

2009 – 2012 Arielle Allen, DO, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of VGEF and PDEF in cystitis in a mouse model.

2010 – 2013 Dena White, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of cytokines, IL6 transgenic mouse model.

2011 – 2014 Edgar LeClaire, MD, FPMRS fellow
Mentored in conduct of research, AUGS Benson Grant project.

2012 – 2015 Stephanie Pickett, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of skeletal muscle type in women with different degrees of prolapse. Identification of cytokine profiles in women with different degrees of prolapse.

2013 – 2016 Benjamin Barenberg, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of satellite cells skeletal muscle regeneration in women with different degrees of prolapse.

2014-2017 Daniel Stone, MD, FPMRS fellow

Mentored in conduct of research, MS thesis in the role of cytokines and macrophages in skeletal muscle regeneration in women with different degrees of prolapse.

2015-2018 Soorena Fatehchehr, MD, FPMRS fellow

VII. Society Memberships

1995-Present (FACOG)	Fellow, American College of Obstetrics and Gynecology
2008-Present	Fellow, American College of Surgeons (FACS) 03135880
2012 – Present	MGMA / ACPME
2011 – Present	The International Society of Ultrasound in Obstetrics and Gynecology
2011 – Present	The American Institute of Ultrasound in Medicine (AIUM)
2008 – Present	The American College of Surgeons (ACS)
2005 – Present	International Continence Society (ICS)
2005 – Present	International Urogynecological Association (IUGA)
1995 – Present	American College of Obstetrics and Gynecology (ACOG)
1994 – Present	American Urogynecological Society (AUGS)

VIII. Committee Memberships

2015- Member of the ICI committee on Imaging and other tests under the chairmanship of Vik Khullar, **6th International Consultation on Incontinence, to be held at the ICS annual meeting in Tokyo, 13th to 14th September 2016**

2015-2018	(IUGA) International Urogynecologic Association Research & Development Committee
2015 – Current	Society of Gynecologic Surgeons Pelvic Floor Anatomy Group
2015 – Current	Working with AIUM / IUGA Ultrasound Practice Accreditation Council and Clinical Standards Committee to develop joint practice and training parameters for pelvic floor imaging.
2015 – Current	IUGA Imaging SIG, working on various international projects
2015 – Present	PFD Research Foundation Grant Reviewer

2010 – 2014	American Federation for Aging Research, National Scientific Advisory Council (NSAC)
2014 - Present	Techniques in Coloproctology, Reviewer
2011 – 2012	The American Urogynecologic Society 2012 Scientific meeting, Program monitor
2011 – Present	Open Journal of Urology, editorial board member
2010 – Present	ACOG Kenneth Gottsfield-Charles Hohler Memorial Foundation Research Award in Ultrasound Committee member
2008 – 2011	The American Urogynecologic Society Annual Scientific Meeting Program Committee
2007 – Present	The American Urogynecologic Society, Abstract Reviewer
2007 – Present	AUGS Basic Science Grant Reviewer
2005 – 2008	The American Urogynecologic Society Research Committee
2011 – Present	The British Journal of Obstetrics and Gynecology, Reviewer
2003 – Present	The International Urogyn Pelvic Floor Dysfunction J, Reviewer
2010 – Present	The Journal of Urology, Reviewer
2009 – Present	American Journal of Obstetrics and Gynecology, Reviewer
2006 – Present	Female Pelvic Medicine and Reconstructive Surgery, Reviewer
2006 – Present	Neurourology and Urodynamics, Reviewer

Hospital / Agency:

2015-Present	Staff Physician Inova Fairfax Hospital, Falls Church, VA
2002-15	Staff Physician OU Medical Center, Oklahoma City, OK
2003-15	Courtesy Staff Physician Integris Baptist Medical Center, Oklahoma City, OK

Licensure

1995-2003	Louisiana	Inactive
2002-	Oklahoma	Active/Current
2015	Virginia	Active

Exhibit B

Clinical Literature

Document Date	Title	Primary Author	Publication
2013-00-00	Correction: Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse		N ENGL J MED 368;4:394
2012-00-00	GUIDE TO LEARNING IN FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY		
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Abbot, et al	Presentation Number: Paper 29
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	Abdel-Fattah, et al	BJU Int, 98(3), 594-598
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111

2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878
2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011l 29:249—253
	Outcome of treatment of anterior vaginal wall prolapse and stress urinary incontinence with Transobturator tension-free vaginal mesh (Prolift) and concomitant tension-free vaginal tape-obturator.	Abou-Elela A, et al.	Adv Urol. 2009:341268. Epub 2008 Dec 25.
2011-00-00	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al	Neurourology and Urodynamics 30:775--782 (2011j
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352

	ACOG Committee Opinion No. 513: vaginal placement of synthetic mesh for pelvic organ prolapse.	ACOG	Obstet Gynecol. 2011;118:1459–1464.
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN - GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and results	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577–583
2014-01-01	Functinal outcomes following surgical managment of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235–239
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2014-00-00	Evaluation of three purely polypropylene meshes of different pore sizes in an onlay position in a New Zealand white rabbit model	Jerabek, et al	Hernia (20141 18:855--864
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	Transvaginal Sling Release With Intraoperative Ultrasound Cuidance	Mukati, Shobeiri	
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2013-04-06	Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence	Nilsson, et al	Int Urogynecol J (2013) 24:1265-1269
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2008-00-00	Surgeons' experience and interaction effect in randomized controlled trials regarding new surgical procedures	Roman, et al	Am J Obstet Gynecol, 199(2), 108 e101-106
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